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Letter Ruling 08-12: Exemption for Drugs on Prescription

September 15, 2008

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You have requested a letter ruling on behalf of your client, ***** [the Taxpayer] concerning the applicability of the Massachusetts sales tax exemption, G.L. c. 64H, § 6(l) to BOTOX Cosmetic, a patented drug manufactured and marketed by the Taxpayer. You specifically request a determination that all prescription sales of BOTOX Cosmetic in the Commonwealth are exempt from Massachusetts sales and use taxes under the cited provision. The factual bases of your request follow and are drawn from your letter of July 23, 2008.

I. FACTS

The Taxpayer is a health care company specializing in developing and manufacturing innovative pharmaceuticals and medical devices and supplies its products, including BOTOX Cosmetic, to physicians, hospitals, clinics and other treatment centers within and outside of Massachusetts.

The scientific term for BOTOX, which has been approved and is regulated by the U.S. Food and Drug Administration [FDA], is “Botulinum Toxin Type A,” the use of which was first approved by the FDA in 1989 under the name “Oculinum” as a treatment for strabismus (abnormal contractions of eye muscles resulting in a deviation in the alignment of one eye from the other), and blepharospasm associated with dystonia (muscle spasms of the eyelid). In 2000, the FDA approved the product under the name “BOTOX” for the treatment of cervical dystonia (intermittent neck muscle spasms). In 2004, the FDA approved BOTOX for the treatment of severe primary axillary hyperhidrosis (underarm sweating). In 2002, the FDA approved the product under the name “BOTOX Cosmetic” to treat moderate to severe dynamic glabellar lines (frown lines) associated with corrugator and/or procerus muscle activity in adult patients aged 65 years and under. In the latter use, Botulinum Toxin Type A prevents the targeted muscles from undergoing the excessive contractions that produce the symptomatic dynamic glabellar lines in the forehead by inducing muscle paralysis.

You state that despite the FDA’s separate labeling nomenclature for various uses of Botulinum Toxin Type A, “Oculinum,” BOTOX,” and “BOTOX Cosmetic,” they are all the same drug carrying different labels.^[1] All are indicated for the treatment of specific medical conditions established by the FDA, and none can be administered except by prescription of a registered physician.

II. ANALYSIS

Massachusetts imposes a five percent sales tax on sales and rentals of tangible personal property in Massachusetts by any vendor, unless otherwise exempt. See G.L. c. 64H, § 2. One of the

exemptions available applies, in pertinent part, to “[s]ales of medicine . . . on prescriptions of registered physicians.” G.L. c. 64H, § 6(l). BOTOX Cosmetic cannot legally be dispensed without a doctor’s prescription. The question, then, is whether the product is a “medicine” within the meaning of the statute.

In DOR Directive 91-5, the Department stated that although Massachusetts tax statutes do not define “medicine,” the Department’s interpretation of the term accords with its common meaning, as evidenced by the definition in Webster’s New Collegiate Dictionary (1979): under that definition, medicine is “a substance or preparation used in treating disease; . . . something that affects well-being.” *Id.* citing Letter Ruling 88-4. See also Letter Ruling 08-3.

In deciding whether BOTOX Cosmetic is a medicine, we begin with the fact that it is specifically approved by the Food and Drug Administration [FDA] to “improve the appearance of moderate to severe frown lines between the eyebrows (glabellar lines), a *medical condition* that is not serious. . . .” *FDA Talk Paper T02-20* (italics supplied). Thus the FDA recognizes that the existence of dynamic glabellar lines is a “medical condition,” and that prescribed use of BOTOX Cosmetic treats this condition and remedies its symptoms. It does this by blocking neuromuscular transmission, binding to acceptor sites on motor nerve terminals, entering the nerve terminals and inhibiting the release of acetylcholine, which is the chemical that causes muscles to contract. The drug thus has a direct, physical effect on the human body, producing a “partial chemical de-enervation of the muscle,” resulting in localized muscle relaxation.”

BOTOX Cosmetic, despite its name, is therefore a medicine within the meaning of the statute. Under the law, the name given to the product is not controlling. Nor is the fact that BOTOX may be used for other, merely cosmetic, purposes (“off label”) of any importance here. The statute is product, rather than use-based. A plain reading of the statute indicates that if the item in question is a medicine prescribed by a registered physician, it is exempt from taxation.^[2]

Our prior rulings are not to the contrary. In DOR Directive No. 91-5, the Department held that substances “used for diagnosis and not for direct medication or treatment of patients” were taxable, even when prescribed by a physician; BOTOX Cosmetic is, however, used not for diagnosis, but for treatment of glabellar lines. In addition, BOTOX Cosmetic is not an implanted medical device, “an inert material and an anesthetic [that] neither treats a disease nor affects the physical condition of the patient. . . .” of the sort that we ruled taxable in LR 08-3. BOTOX Cosmetic has a therapeutic effect on the human body.

III. Ruling

BOTOX cosmetic is exempt from the Massachusetts sales and use tax pursuant to G.L. c. 64H, § 6(l) if prescribed by a registered physician.

Very truly yours,

/s/Navjeet K. Bal

Navjeet K. Bal
Commissioner of Revenue

NKB:MTF:lr

LR 08-12

^[1] The variously named forms of BOTOX are in fact interchangeable, so long as dosing and procedure requirements are adhered to.

^[2] We have noted that the FDA describes the condition for which BOTOX Cosmetic is approved as “not serious,” but the statute does not require that the “condition” for which medicine is prescribed be

serious, or even that the medicine be prescribed for disease *per se*. Thus the Department has exempted sales of normally taxable over-the-counter medications (*e.g.*, aspirin) when sold on prescription. See DD 86-32.